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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/204,236	12/03/1998	GREGORY S. HAMILTON	087579-0202	5251

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GUILFORD PHARMACEUTICALS C/O
FOLEY & LARDNER LLP
3000 K STREET, NW
WASHINGTON, DC 20007-5143

EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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01/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/204,236

Applicant(s)

HAMILTON ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 90,92-96,99,101-105 and 108-111 is/are pending in the application.
- 4a) Of the above claim(s) 97-98,106-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application is a RCE of SN 09/204,236.

Claims 90, 92-96, 99, 101-105, and 108-111 are pending. Claims 97-98, 106-107 stayed withdrawn per 37 CFR 1.1429b).

2. Claims 90 and 99 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description as well as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention; and the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In the specification on page 15, description of various salts of the compounds without any description of which compounds will form what solvates or with which solvents a solvate can form. The specification contains none of the compound, which is a solvate. While a pharmaceutical addition salt can be prepared routinely upon in possession of an acid or basic compound, the solvate formation is the innate nature of a compound upon contacting certain solvent. Without any description of what solvent will form solvate with which compound and completely silent of the existence of any solvate or hydrate, the specification offered mere language rather than possession or enablement of the solvates.

Solvates are different chemical compounds from non-solvated compounds. It is conventional knowledge in the chemical art that solvates which are different chemical identity (Seddon) and in possession of a compound per se rendered no predictability of existence and in possession of its solvates (Braga) because no predictability can be offered to what kind of a solvate a compound may or may not form. Applicants argued that "solvates" is a well-known term. Such argument does not provide enablement for any solvate existed or can be made and can be tested for activity in treating any and all neurological disorder. As a matter of fact, the term "solvate" although known to chemist, does not automatically enable one skilled in the art to prepare them. A state of the art reference is hereby provided for applicants' convenience, it is

clearly stated by chemists that "one can say that if the formation of polymorphs is a nuisance for crystal engineers, *solvate formation* can be a nightmare..." (see Braga et al. p.3640). In the entire specification, not one solvate has been prepared nor was there any description of what kind of solvate can be prepared.

Applicants attention is drawn to that the exhibit supposedly being attached to the remark of applicants dated Oct. 26, 2007 was not found in the electronic file. The two US patents have been acquired by the examiner wherein both patents are specifically disclosed processes for making the specific solvates which are the described inventions. Contrary to the recited patents, the instant application provided mere term "solvates thereof" without any description of what solvent will form solvate with which compound and completely silent of the existence of any solvate, therefore, no enablement for such products. Attorney provided no basis why another person made a solvated compound thus is entitle to claim that compound while the instant specification made no such compound but should be given one irrespective of what it is.

3. Claims 92-96, 101-105, and 108-111 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Based on description and data of tables II and III, the claimed compounds have been described to have in vivo neuronal regeneration and growth activity for which the claims have been limited to.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

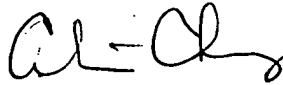
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan. 22, 2008.



Celia Chang
Primary Examiner
Art Unit 1625